

## Record of Amendments to “Drugs for Chronic Hepatitis C Infection: Clinical Review Report”

Change #	Page	January 2016 version	Revised (June 2016) version
1	xxii, paragraph 2	Once again, there were no significant differences between SOF + LDV and PAR/RIT + OMB + DAS ± RBV, and in some cases these regimens were superior to DCV-based regimens (in particular, PAR/RIT + OMB + DAS ± RBV was generally better for genotype 1b and for patients without cirrhosis).	Once again, there were no significant differences between SOF + LDV and PAR/RIT + OMB + DAS ± RBV, with two exceptions: in the subgroup analysis of patients without cirrhosis, PAR/RIT + OMB + DAS + RBV for 12 weeks significantly improved SVR compared with SOF + LDV for 12 weeks; and in the subgroup analysis of patients with genotype 1b infection, PAR/RIT + OMB + DAS for 12 weeks significantly improved SVR compared with SOF + LDV for 12 weeks. In some cases PAR/RIT + OMB + DAS ± RBV was superior to DCV-based regimens (in particular, for patients without cirrhosis, and patients with genotype 1b infection).
2	xxiv, Exhibit 1 (row 3, column 3)	PR48 SIM12 + PR24-48 RGT	PR48 SIM12 + PR24-48 RGT SOF12 + LDV12 DCV24 + ASU24
3	47, paragraph 3	PAR/RIT12 + OMB12 + DAS12 significantly improved SVR compared with SIM12 + PR24-48 RGT, and SOF12 + LDV12	PAR/RIT12 + OMB12 + DAS12 significantly improved SVR compared with SIM12 + PR24-48 RGT, DCV24 + ASU24, and SOF12 + LDV12
4	126, paragraph 4	For treatment-experienced patients, all three regimens were superior to PR based treatments, in particular SOF + LDV and PAR/RIT + OMB + DAS. There was limited evidence for patients with cirrhosis. In some cases, SOF + LDV and PAR/RIT + OMB + DAS were better than DCV-based regimens (in particular, PAR/RIT + OMB + DAS was better for genotype 1b and for patients without cirrhosis).	For treatment-experienced patients, all three regimens were superior to PR based treatments, in particular SOF + LDV and PAR/RIT + OMB + DAS. There was limited evidence for patients with cirrhosis. There were no significant differences between SOF + LDV and PAR/RIT + OMB + DAS ± RBV, with two exceptions: in the subgroup analysis of patients without cirrhosis, PAR/RIT + OMB + DAS + RBV for 12 weeks significantly improved SVR compared with SOF + LDV for 12 weeks; and in the subgroup analysis of patients with genotype 1b infection, PAR/RIT + OMB + DAS for 12 weeks significantly improved SVR compared with SOF + LDV for 12 weeks. In some cases, SOF + LDV and PAR/RIT + OMB + DAS were better than DCV-based regimens (in particular, PAR/RIT + OMB + DAS was better for genotype 1b and for patients without cirrhosis).

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5	127, Exhibit 4 (row 12, column 3)	PR48 SIM12 + PR24-48 RGT	PR48 SIM12 + PR24-48 RGT SOF12 + LDV12 DCV24 + ASU24